Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-1038

JUN 05 2020

TO : **ALL HOSPITALS AND HEALTHCARE PROVIDERS**

SUBJECT : **Risks Associated with the Use of Favipiravir**

The Food and Drug Administration (FDA) reminds all hospitals and healthcare providers to take extreme caution on the use of Favipiravir. The product has been observed to have teratogenic and embryotoxic effects in animal studies.[1,4] Its use is contraindicated in known or suspected pregnancy.

The FDA advises the licensed physicians to confirm a negative pregnancy test before using Favipiravir in women with child-bearing potential. They should be advised to use or continue using effective contraceptive methods while in use and for another seven (7) days after taking the last dose. If pregnancy is suspected, discontinue its use.[1,2]

Favipiravir is distributed in the sperm. Male patients should be informed of the risk associated on the use of the product. Instruct the patients to use the most effective contraceptive methods while using the product and for another seven (7) days after the last dose. Advise the use of condom and instruct not to have sexual intercourse with pregnant women.[1,2]

Physicians are also advised to carefully monitor patients for other possible adverse effects such as increase in blood uric acid level, diarrhea, decrease in neutrophil count, and elevated liver enzymes – alanine aminotransferase (ALT) & aspartate aminotransferase (AST).[1]

The benefit-risk balance should be carefully assessed prior to considering the use of the drug. Risks associated with the drug must be fully explained to patients.[3]

All are enjoined to report adverse drug reactions (ADR) to FDA through this link: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH and fill out all the required fields. All hospitals with VigiFlow accounts are encouraged to report in the said platform. For inquiries email us at pharmacovigilance@fda.gov.ph.

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Director General

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References
Adverse events were taken from the drug insert
[1]Favipiravir (Haifukang) Tablets product information
[2]Favipiravir (Avigan) Tablets 200 mg prescribing information. Retrieved 19 May 2020 from https://www.cdc.gov.tw/File/Get/ht8jUiB_MI-aKnlwstwzvw.
[3]World Health Organization. (2020). WHO R&D Blueprint. In M. Cavaleri (Chair), *COVID-19: Informal consultation on the potential inclusion of Favipiravir in a clinical trial* (draft). Geneva, Switzerland.
[4]Favipiravir (Avigan) Tablet 200 mg Review Reports (March 2014), Pharmaceuticals and Medical Devices Agency. Retrieved 26 May 2020 from https://www.pmda.go.jp/files/000210319.pdf

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